

Amendments to the Claims

This listing of claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims:

1. (Currently Amended) A simulator system comprising:
 - a manikin including a simulated body cavity or lumen and an interface device;
 - a medical device having a first end for manipulation by a first user and a portion having a second end that is insertable into the simulated body cavity or body lumen, wherein the simulator system simulates the use and movement of the medical device in the simulated body cavity or lumen of the manikin;
 - wherein the interface device is configured to receive the medical device portion having the second end and to also interface with the simulated body cavity or lumen, and
 - wherein the interface device includes an active directional force feedback mechanism, the active directional force feedback mechanism being configured so as to exert a directional force directly on the medical device portion in response to a feedback signal received by the force feedback mechanism;
 - a computational engine embodying physically based modeling using finite element methodology, the computational engine simulating interactions between the medical device and body cavity or lumen, the interactions relating to the manipulation of the medical device by the first user; ~~and~~
 - wherein the computational engine models interactions between the medical device and the body cavity or lumen in three-dimensions, computes forces that would arise from interactions between the medical device and body cavity or lumen and outputs feedback signals corresponding to the computer forces to the active directional force feedback mechanism so as to thereby feedback said computed forces to the user; and
 - a tactile feedback mechanism that is selectively coupled to the medical device so as to simulate forces being exerted on the medical device, these simulated forces being different from

the directional forces associated with interactions between the medical device and the body cavity or lumen.

2. (Previously Presented) The simulator system according to claim 1, wherein the active directional force feedback mechanism is configured so as to provide resistance to forward motion but enables free reverse motion in response to the feedback signal.
3. (Previously Presented) The simulator system according to claim 1, wherein the active directional force feedback mechanism includes a rolling element that is coupled to the medical device portion having the second end and wherein an internal surface of the simulated cavity or lumen in the manikin includes an oblique slot and wherein the active directional force feedback mechanism is arranged so that the rolling element is receivable in the oblique slot.
4. (Previously Presented) The simulator system according to claim 3, wherein, in response to a feedback signal, forward movement of the medical device second end causes the rolling element to be received by the slot, thereby causing resistance to further forward motion.
5. (Previously Presented) The simulator system according to claim 4, wherein the active directional force feedback mechanism includes a motor, where the motor controls movement of the rolling element.
6. (Canceled)
7. (Currently Amended) The simulator system according to claim 1, ~~claim 6~~, wherein the tactile feedback mechanism is responsive to inputs corresponding to the simulated forces

being exerted on the medical device, wherein the tactile feedback mechanism is configured so as to provide continuous oscillatory feedback to a user holding the medical device to simulate medical device motion induced by the simulated forces being exerted on the medical device.

8. (Previously Presented) The simulator system according to claim 7, wherein the tactile feedback mechanism includes a continuously rotating motor and wherein the continuous oscillatory feedback is provided through the continuously rotating motor in operable contact with the medical device portion including the second end.
9. (Previously Presented) The simulator system according to claim 1, further comprising a user display and a tracking device for continuously tracking a position of at least the medical device second end relative to the simulated body cavity or lumen within the manikin, wherein the user display displays the simulated body cavity or lumen and the medical device based on its relative position and movement.
10. (Previously Presented) The simulator system according to claim 9, wherein the tracking device comprises an encoder for tracking the translation of the medical device and an encoder for tracking the rotation of the medical device, the translation and rotational encoders being embodied in the medical device.
11. (Previously Presented) The simulator system according to claim 9, wherein the tracking device comprises an optical tracking unit embodied in the manikin, the optical tracking unit including a light source, a signal processing circuit, and one or more optical sensors, wherein the optical tracking unit is placed within the interface device so as to be in optical communication with the medical device when it is inserted into the simulated cavity or lumen.

12. (Previously Presented) The simulator system according to claim 11, wherein light from the light source reflects from the medical device when it is inserted and wherein the reflected light is received by the one or more optical sensors.
13. (Previously Presented) The simulator system according to claim 12, wherein changes in reflected light received by the one or more sensors is detected and outputs are provided to the computational engine, and wherein, in response to these outputs, the computational engine simulates movement of the medical device in real-time and displays such simulated movement on the user display.
14. (Previously Presented) The simulator system according to claim 12, wherein two optical sensors are provided which are perpendicular to one another.
15. (Previously Presented) The simulator system according to claim 12, wherein the optical tracking unit is configured in the form of a rail along which the medical device can move.
16. (Previously Presented) The simulator system according to claim 9, wherein:
one or more additional medical devices are inserted into the interface device, each of said one or more additional medical devices includes a first end for manipulation by a user and a portion including a second end for insertion into the simulated body cavity or body lumen,
the position relative to the simulated body cavity or lumen of each of the one or more additional medical device inserted into the interface device is independently tracked, and
the display displays the relative position and movement of each of the one or more additional medical devices and the simulated body cavity or lumen.

17. (Previously Presented) The simulator system according to claim 16, wherein the medical device and the one or more additional medical devices are each selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.
18. (Previously Presented) The simulator system according to claim 1, further includes a table for placing the manikin thereon, wherein the table comprises a processor connectable to a network.
19. (Previously Presented) The simulator system according to claim 1, wherein the simulator system further comprises at least one first user device being operably coupled to the computational engine, wherein the first user device includes a first display device that displays a three-dimensional representation of the simulated body cavity or lumen of a patient.
20. (Previously Presented) The simulator system according to claim 19, wherein the first display device further displays a three-dimensional representation of the medical device along with the simulated body cavity or lumen and wherein the computational engine simulates the movement of the medical device within the simulated body cavity or lumen of the manikin in real-time as a first user manipulates the medical device in the simulated body cavity or lumen within and causes such simulations to be displayed on the first display device.
20. (Canceled)

21. (Previously Presented) The simulator system according to claim 19, further comprising a simulated scanning display that displays an image that is representative of one of a two-dimensional scanned image or a three-dimensional reconstructed scanned image of the simulated body cavity or lumen.
22. (Previously Presented) The simulator system according to claim 21, further comprising a simulated scanning device and wherein the simulated scanning display is part of the simulated scanning device.
23. (Previously Presented) The simulator system according to claim 22, wherein the simulated scanning device is simulating one of an x-ray imaging system, an MRI imaging system or an ultrasonic imaging system.
24. (Previously Presented) The simulator system according to claim 22, wherein the simulated scanning device and scanning display are coupled to a movable C-arm of an x-ray imaging system within scanning distance of the manikin.
25. (Previously Presented) The simulator system according to claim 1, further comprising a re-configurable control panel for performing one or more of: image acquisition selection; image display; manipulating a table on which the manikin is placed; manipulating the position of a simulated scanning device relative to the manikin; and control of one or more shutter devices for limiting a field of view of the simulated scanning device when placed within scanning distance of the manikin.
26. (Previously Presented) The simulator system according to claim 1 or 20, further comprising a monitoring station, the monitoring station including a second user device

and a second display interface for enabling a second user to monitor the movement of the medical device within the simulated body cavity or lumen.

27. (Previously Presented) The simulator system according to claim 26, wherein the second display interface of the monitoring station displays selectable options enabling the second user to select or change one or more anatomical and/or physiological parameters of the simulated body cavity or lumen, and wherein the selection causes a three-dimensional image of the simulated body cavity or lumen being displayed to a first user to change to reflect the changed anatomical and/or physiological parameters.
28. (Previously Presented) The simulator system according to claim 20, wherein the computational engine is operably coupled to a database of patient images and/or medical data so the patient images and/or medical data can be obtained and displayed to the first user.
29. (Previously Presented) The simulator system according to claim 26, wherein the computational engine is operably coupled to a database of patient images and/or medical data so the patient images and/or medical data can be obtained and displayed to the first user.
30. (Previously Presented) The simulator system according to claim 28, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.
31. (Previously Presented) The simulator system according to claim 29, wherein the patient images comprise images of a body cavity or lumen from a patient affected by a pathology.

32. (Previously Presented) The simulator system according to claim 22, further comprising at least one foot-activation switch for activating or collimating the simulated scanning device, image display or table movement.
33. (Previously Presented) The simulator system according to claim 28, wherein the first user device is configured so as to allow the first user to access the database of patient images and/ or medical data, and wherein, in response to said accessing, the requested image and/or medical data is displayed on the first user display device.
34. (Previously Presented) The simulator system according to claim 29, wherein the second display interface is configured so as to allow the second user to access the database of patient images and/ or medical data, and wherein, in response to said accessing, the requested image and/or medical data is displayed on the second display interface.
35. (Previously Presented) The simulator system according to claim 33, further comprising a monitoring station that includes a second user device and a second display interface to enable a second user to monitor the movement of the medical device within the simulated body cavity or lumen. and wherein the second display interface is configured so as to allow the second user to access the database of patient images and/ or medical data, and wherein, in response to said accessing, the requested image and/or medical data are displayed on the second display interface.
36. (Previously Presented) The simulator system according to claim 35, wherein the second display interface provides a selectable option enabling a second user to display the image displayed on the second display interface, on the first display device.

37. (Previously Presented) The simulator system according to claim 1, wherein the medical device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

Claims 38 - 43 (Cancelled)

44. (Currently Amended) The simulator system according to claim 1, wherein the medical device comprises a syringe that simulates fluid delivery, the syringe includes:
- a housing defining a lumen comprising an opening for delivering a fluid;
 - a pushing element for pushing the fluid through the opening;
 - a friction-producing element in communication with the pushing element; and
 - a motor in communication with the friction-producing element and comprising a signal-receiving element,
- wherein the friction-producing element causes friction between the pushing element and a surface of the lumen of the housing upon activation by the motor in response to a signal received by the signal-receiving element, and further
- wherein the opening of the syringe is connectable to a connecting piece having a first end for receiving fluid from the opening and a second end for delivering fluid to the simulated body cavity or body lumen in the manikin.

45. (Cancelled)

46. (Previously Presented) The simulator system according to claim 1, wherein the medical device comprises a balloon-inflating device that simulates deployment of a balloon within the body cavity or lumen of the patient, the balloon-inflating device comprising:
- a delivery mechanism for controlling delivery of fluid through the balloon-inflating device to the balloon;
 - a pressure sensor for monitoring pressure of a fluid delivered to the balloon by the balloon-inflating device;
 - an electrical pressure meter for reading pressure determined by the pressure sensor, the electrical pressure meter being connectable to a processor and for transmitting a signal corresponding to a pressure value to the processor.
47. (Previously Presented) The simulator system according to claim 20, wherein the computational engine simulates deformation of the simulated body cavity or lumen by the medical device.
48. (Previously Presented) The simulator system according to claim 20, wherein the the computational engine simulates an operation of a medical device selected from the group consisting of: a surgical procedure, inflation or deflation of a balloon, injection of a radioopaque material into the body cavity or lumen, and combinations thereof.
49. (Previously Presented) The simulator system according to claim 20, wherein the computational engine simulates the movement of the medical device within a blood vessel.
50. (Previously Presented) The simulator system according to claim 49, wherein the blood vessel is one of in or of an organ of the patient.

51. (Previously Presented) The simulator system according to claim 49, wherein the blood vessel is in one of the heart or the brain.
52. (Currently Amended) A method for simulating the use and movement of a medical device in a body cavity or lumen of a patient, the method comprising the steps of:
- providing a medical device;
 - providing a simulacrum having a simulated body cavity or body lumen within the simulacrum, ~~and an active directional force feedback mechanism~~ and a tactile feedback mechanism that are ~~that is~~ disposed in the simulated body cavity or lumen,
 - wherein the provided medical device has a first end for manipulation by a first user and a portion including a second end that is to be inserted into the simulated body cavity or body lumen and wherein the active directional force feedback mechanism is configured to receive therein, and act directly thereon on, the medical device portion including the second end so as to create resistance to forward motion of the medical device responsive to inputted feedback signals and to allow free reverse motion,
 - inserting the portion of the provided medical device into the simulated body cavity or lumen,
 - performing physically based modeling using a finite element methodology to simulate interactions between the medical device and body cavity or lumen,
 - computing forces that would arise from the interactions between the medical device and body cavity or lumen,
 - outputting feedback signals to the active directional force feedback mechanism responsive to the computed forces, ~~and~~
 - using the active directional force feedback mechanism responsive to the outputted feedback signals to act directly on the medical device portion including the second end so as to create resistance to forward motion of the medical device so as to thereby feedback the computed forces to the first user;

wherein the tactile feedback mechanism is configured so as to be responsive to other inputted feedback signals and to provide continuous oscillatory feedback to a first user manipulating the medical device to simulate medical device motion induced by simulated forces being exerted on the medical device; and
using the tactile feedback mechanism to provide oscillatory feedback during said inserting.

53. (Previously Presented) The method according to claim 52, further comprising the step of: providing a system that includes:
- a processor in communication with the active directional force feedback mechanism; and
 - a first user device operably coupled to the processor, the first user device comprising a first display interface for displaying a representation of a body cavity or lumen; and for providing access to a database of three-dimensional images of body cavities and lumens from a plurality of different patients; and
 - enabling the first user to select from the database a representation, wherein in response to the selection, the representation is displayed on the first display interface.
54. (Previously Presented) The method according to claim 53, wherein the first display interface displays a three-dimensional representation of the medical device and wherein the system simulates the movement of the medical device within the simulated body cavity or lumen in real-time as a first user manipulates the medical device within the simulated body cavity or lumen.

55. (Previously Presented) The method according to claim 53 or 54, further comprising the step of:
providing a monitoring station that includes a second display interface in communication with the processor and the first display interface, and wherein the second display interface provides a second user with access to the database.
56. (Previously Presented) The method according to claim 55, further comprising the steps of:
having a second user select a representation from the database, and
causing the representation to be displayed on both the first and second display interfaces.
57. (Previously Presented) The method according to claim 53, further comprising the steps of:
simulating the deformation of the simulated body cavity or lumen in response to manipulation of the medical device in the simulated body cavity or lumen by the first user, and
displaying the representation of the deformation on the first display interface.
58. (Previously Presented) The method according to claim 53, further comprising the steps of:
performing an operation on the simulated body cavity or lumen using the medical device, and
displaying a simulation of the operation on the first display interface.
59. (Previously Presented) The method according to claim 58, wherein said performing includes one of inflating or deflating a balloon within the simulated body cavity or lumen.

60. (Previously Presented) The method according to claim 58, wherein said performing includes injecting a radioopaque fluid within the body cavity or lumen.
61. (Previously Presented) The method according to claim 52, wherein the provided medical device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, an optical probe, a drug delivery device, and combinations thereof.
62. (Previously Presented) The method according to claim 54, further comprising the steps of:
providing one or more additional medical devices,
inserting the provided one or more additional medical devices into the simulated body cavity or lumen, and
independently monitoring and displaying the movement of each inserted medical device.
63. (Canceled)
Claims 64 -73 (Cancelled)
74. (Currently Amended) A simulator system comprising:
a simulacrum of a patient, the simulacrum including a simulated body cavity or lumen, ~~and an interface device that is configured to interface with the simulated body cavity or lumen~~ and a tactile feedback mechanism that is disposed in said body cavity or lumen;
a medical device having a first end for manipulation by a first user and a portion including a second end that is insertable into the simulated body cavity or

body lumen, where the simulator system simulates use and movement of the medical device in the simulated body cavity or lumen;

wherein the interface device is configured to receive the medical device portion including the second end,

wherein the interface device includes an active feedback mechanism that is configured so as to be selectively, operably, directly coupled to the medical device and so as to provide continuous oscillatory feedback to the medical device;

a computational engine for physically based modeling using finite element methodology, the computational engine simulating interactions between the medical device and the simulated body cavity or lumen;

wherein the computational engine models interactions between the medical device and the simulated body cavity or lumen in three-dimensions, computes forces that would arise from interactions between the medical device and the simulated body cavity or lumen and feeds back signals to the interface device so as to thereby feedback said forces to the first user via the medical device; ~~and~~

at least one first display device being operably coupled to the computational engine and for displaying a three-dimensional representation of the simulated body cavity or lumen and a three-dimensional representation of the medical device within the simulated body cavity or lumen;

wherein the computational engine further simulates movement of the medical device within the simulated body cavity or lumen in real-time as the first user manipulates the medical device within the simulated body cavity or lumen and causes such simulations to be displayed on the first display device; and

wherein the tactile feedback mechanism is selectively coupled to the medical device so as to provide a continuous oscillatory feedback to the first user holding the medical

device to simulate medical device motion induced by simulated forces being exerted on the medical device by physiological parameters, these simulated forces being different from the directional forces associated with interactions between the medical device and the body cavity or lumen.

75. (Currently Amended) A simulator system comprising:

a simulacrum of a patient, the simulacrum including a simulated body cavity or lumen, ~~and~~ an interface device configured to interface with the simulated body cavity or lumen and a tactile feedback mechanism that is disposed in said body cavity or lumen;

a medical device having a first end for manipulation by a first user and a second portion including a second end that is insertable into the simulated body cavity or body lumen, where the simulator system simulates use and movement of the medical device in the simulated body cavity or lumen;

wherein the interface device is configured to receive the second portion including the second end;

a processor for simulating real-time movement of the medical device with the simulated body cavity or lumen as the first user manipulates the medical device, wherein deformation of the simulated body cavity or lumen in response to blood flow or the movement of the medical device is modeled using physically based modeling embodying finite element methodology in real-time;

wherein the processor computes forces that would arise from interactions between the medical device and body cavity or lumen and provides a feedback signal to the interface device for simulating said forces to the first user;

at least one first display device being operably coupled to the processor engine and for displaying a three-dimensional representation of the simulated

body cavity or lumen and a three-dimensional representation of the medical device within the simulated body cavity or lumen;

wherein the processor causes the simulated real-time movement of the medical device within the simulated body cavity or lumen and the real time deformation of the simulated body cavity or lumen in response to blood flow or the movement of the medical device to be displayed on the first display device; and

wherein the tactile feedback mechanism is selectively coupled to the medical device so as to simulate forces being exerted on the medical device, these simulated forces being different from the directional forces associated with interactions between the medical device and the body cavity or lumen.

76. (Previously Presented) The simulator system according to any of claims 1, 74, or 75, wherein one of the computational engine or the processor alters a finite element structure corresponding to the medical device and/or body cavity or lumen in response to a manipulation of the medical device by the first user.

77. (Previously Presented) The simulator system according to any of claims 1, 74, 75, wherein:

the simulated body cavity or lumen is a simulated blood vessel of a vascular system; and the system models interactions, using said one of the computational engine or the processor, between the medical device and a wall of the blood vessel and computes forces that would arise from the interactions between the device and the vessel wall and feeds back signals to the interface device so as to thereby feed back such computed forces back to the first user.

78. (Previously Presented) The simulator system according to claim 77, wherein the one of the computational engine or the processor simulates a path that represents at least a portion of the

vascular system and determines a fit between geomtery of the medical device and the geometry of the simulated path.

79. (Previously Presented) The simulator system of claim 77, wherein the blood vessel is modeled in the one of the computational engine or the processor as one of a rigid cylindrical body or a deformable structure to reflect a pathology of the blood vessel.

80. (Previously Presented) The simulator system of claim 77, wherein the system further includes modeling interactions between the medical device and flow of blood in the blood vessel.

81. (Previously Presented) The method according to claim 52, further comprising the step of; altering a finite element structure corresponding to the medical device and/or body cavity or lumen in response to a manipulation of the medical device by the first user.

82. (Previously Presented) The method of claim 52, wherein:
the simulated body cavity or luman is a simulated blood vessel of a simulated vascular system;

said inserting includes inserting the portion of the provided medical device by the first user into the simulated blood vessel,

said performing physically based modeling includes performing physically based modeling to simulate interactions between the medical device and a wall of the simulated blood vessel; and

said computing forces includes computing forces that arise from interactions between the medical device and the simulated blood verssel.

83. (Previously Presented) The method of claim 82, wherein said performing physically based modeling includes simulating a path that represents at least a portion of the simulated

vascular system and determining a fit between the geometry of the medical device and the geometry of the simulated path.

84. (Previously Presented) The method of claim 82, wherein said performing physically based modeling includes performing physically based modeling of the simulated blood vessel as one of a rigid cylindrical structure or a deformable structure to reflect a pathology.

85. (Previously Presented) The method of claim 82, further comprising:
modeling of interactions between the medical device and flow of blood in the simulated blood vessel and providing a feed back of such interactions to the first user via the medical device.

86. (Previously Presented) The simulator system according to claim 1, wherein:
the simulated body lumen is a simulated blood vessel of a simulated vascular system;
the computational engine embodying physically based modeling simulating interactions between the medical device and the simulated blood vessel; and
the system models interactions, using said computational engine, between the medical device and a wall of the simulated blood vessel and computes forces that would arise from the interactions between the medical device and the vessel wall and feeds back such computed forces back to the first user via the medical device.

87. (Previously Presented) The simulator system according to claim 86, wherein the medical device is selected from the group consisting of a catheter, guidewire, endoscope, laparoscope, bronchoscope, stent, coil, balloon, a balloon-inflating device, a surgical tool, a vascular occlusion device, optical probe, a drug delivery device, and combinations thereof.

88. (Currently Amended) The simulator system according to claim 7 wherein the tactile feedback mechanism provides a continuous oscillatory feedback to the a-first user holding the medical device to simulate medical device motion induced by simulated forces being exerted on the medical device by physiological paramters.

89. (Currently Amended) The method according to claim 63 wherein the tactile feedback mechanism provides a continuous oscillatory feedback to the a-first user holding the medical device to simulate medical device motion induced by simulated forces being exerted on the medical device by physiological paramters.

90. (New) The simulator system according to claim 75 wherein the tactile feedback mechanism provides a continuous oscillatory feedback to the first user holding the medical device to simulate medical device motion induced by simulated forces being exerted on the medical device by physiological paramters.